



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1092]

Minimizing Risk for Children's Toy Laser Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Minimizing Risk for Children's Toy Laser Products." This draft guidance is to inform manufacturers of laser products, FDA headquarters and field personnel, and the public of the Center for Devices and Radiological Health's (CDRH) proposed approach on the safety of toy laser products. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Minimizing Risk for Children's Toy Laser Products" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your

request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert J. Doyle, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4672, Silver Spring, MD 20993-0002, 301-796-5863.

## I. Background

This draft guidance is to inform manufacturers of laser products, FDA headquarters and field personnel, and the public of CDRH's proposed approach on the safety of children's toy laser products. Lasers with outputs above certain levels that are operated in an unsafe and uncontrolled manner may cause injury to the user and/or others within range of the laser beam. This is a particular concern for lasers intended for entertainment purposes, especially when intended to be used as toys by children. Although Federal law requires all laser products sold in the United States to be in compliance with the Federal Performance Standards for Laser Products (21 CFR 1040.10 and 1040.11), at present FDA regulations do not specifically address children's toy laser products. FDA recently issued a proposed rule (78 FR 37723) that proposes to define children's toy laser products and require them to be within International Electrotechnical Commission (IEC) Class 1 emission limits. While this rulemaking process is ongoing, CDRH encourages manufacturers to keep children's toy laser products within IEC Class 1 emission limits in order to minimize the risk they pose to this vulnerable population.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's proposed approach on children's toys that are or that contain laser products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Minimizing Risk for Children's Toy Laser Products," you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1810 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>.

## IV. Paperwork Reduction Act of 1995

This draft guidance refers to a currently approved collection of information found in FDA regulations. This collection of information is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in 21 CFR part 1040 is approved under OMB control number 0910-0025.

## V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments regarding this document to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: August 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-19018 Filed 08/06/2013 at 8:45 am; Publication Date: 08/07/2013]